K080072

JUN - 4 2008

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k): CIVCO Medical
102 First Street South
Kalona, IA 52247-9589
USA

Phone: 319-656-4447
Fax: 877-218-0324

Contact Person: Jim Leong

Date of Summary: December 17, 2007

Trade/Proprietary Name: MRI Patient Positioning Devices

Classification Name: MRI Patient Positioning Devices

Product Code: IXQ
IYE

Intended Use:
Patient Positioning Devices are used to aid in the support and positioning of patients during an MRI.

Device Description:
The Civco Patient Support Devices have been used for many years and were previously cleared under 510(k)'s before the classification was reduced to Class I exempt. This 510(k) is to have these identical Class I products cleared for use in an MRI environment.

Predicate Devices:

K973842 - Medtec Inc, Carbon Fiber Conformal Couch Top
K951808 – Medtec Inc, Med-Tec Redi-Foam
K982624 – Medtec Inc, Moldcare Head & Neck Cushion
K933227 – Medtec Inc, Uni-Frame Head Immobilization System
K935300 – Medtec Inc , Vac-Lok Immobilizatioin System

Substantial Equivelance:

CIVCO Medical Instruments claims the proposed devices to be substantially equivalent to the devices previously cleared by FDA in the following 510k's K973842, K951808, K982624, K933227 and K953300. CIVCO Medical Instruments claims this equivalence because the proposed devices have equivalent intended uses, manufacturing materials, operating principals, and physical, operational specifications as compared to the predicate devices.

There are no signigficant differences between the proposed and predicate devices except that they have now been tested for use in an MRI environment. The product labeling, including brochures has been updated. These differences have no effect on safety and effectiveness. These products have been tested to demonstrate that they can be safely used in an MRI environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2008

CIVCO Medical Instruments Co., Inc.
% Arthur Ward, Ph.D.
Consultant
AJW Technology Consulting, Inc.
962 Allegro Lane
APOLLO BEACH FL 33572

Re: K080072
Trade/Device Name: MRI Patient Positioning Device
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: April 21, 2008
Received: April 30, 2008

Dear Dr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080072

Device Name: MRI Patient Positioning Devices

Indications for Use:

Patient Positioning Devices are used to aid in the support and positioning of patients during an MRI.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080072